**Policy Statement**

Screening for vertebral fractures using dual-energy x-ray absorptiometry is considered investigational.

**Policy Guidelines**

The CPT coding for this procedure depends on whether it is performed with dual-energy x-ray absorptiometry:

- **77085**: Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (e.g., hips, pelvis, spine), including vertebral fracture assessment
- **77086**: Vertebral fracture assessment via dual-energy X-ray absorptiometry (DXA)

**Description**

Vertebral fracture assessment (VFA) with densitometry is a technique to assess vertebral fractures at the same time as bone mineral density, using additional software with dual-energy x-ray absorptiometry. The addition of VFA to bone mineral density may augment diagnostic information on fracture risk.

**Related Policies**

- Bone Mineral Density Studies
- Whole Body Dual X-Ray Absorptiometry to Determine Body Composition

**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates [e.g., Federal Employee Program (FEP)] prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

**Regulatory Status**

Additional software is needed to perform VFA with a densitometer, and it must be cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process. Products cleared for marketing include Lunar Dual Energy Vertebral Assessment (DVA™; General Electric Medical Systems) and Instant Vertebral Assessment™ (IVA™; Hologic) software. Food and Drug Administration product code KGI.
Rationale

Background
Vertebral Fractures
Vertebral fractures are highly prevalent in the elderly population, and epidemiologic studies have found that these fractures are associated with an increased risk of future spine or hip fractures independent of bone mineral density.

Diagnosis
Only 20% to 30% of vertebral fractures are recognized clinically; the rest are discovered incidentally on lateral spine radiographs. Lateral spine radiographs have not been recommended as a component of risk assessment for osteoporosis because of the cost, radiation exposure, and the fact that the radiograph would require a separate procedure in addition to the bone mineral density study using dual-energy x-ray absorptiometry. However, several densitometers with specialized software can perform vertebral fracture assessment (VFA) in conjunction with dual-energy x-ray absorptiometry. The lateral spine scan is performed by using a rotating arm; depending on the densitometer used, the patient can either stay in the supine position after the bone density study or is required to move to the left decubitus position.

VFA differs from radiologic detection of fractures because VFA uses a lower radiation exposure and can detect only fractures, while traditional radiograph images can detect other bone and soft tissue abnormalities in addition to spinal fractures. Manufacturers have also referred to this procedure as instant vertebral assessment, radiographic vertebral assessment, dual-energy vertebral assessment, or lateral vertebral assessment.

For both lateral spine radiographs and images with densitometry, vertebral fractures are assessed visually. While a number of grading systems have been proposed, the Genant semiquantitative method is commonly used. This system grades deformities from I to III, with grade I (mild) representing a 20% to 24% reduction in vertebral height, grade II (moderate) representing a 25% to 39% reduction in height, and grade III (severe) representing a 40% or greater reduction in height. The location of the deformity within the vertebrae may also be noted. For example, if only the mid height of the vertebrae is affected, the deformity is defined as an endplate deformity; if both the anterior and mid heights are deformed, it is a wedge deformity; and if the entire vertebrae is deformed, it is classed as a crush deformity. A vertebral deformity of at least 20% loss in height is typically considered a fracture. Accurate interpretation of both lateral spine radiographs and VFA imaging is dependent on radiologic training. Thus, device location and availability of appropriately trained personnel may influence diagnostic accuracy.

Literature Review
Assessment of a diagnostic technology typically focuses on 3 categories of evidence: (1) its technical reliability (test-retest reliability or interrater reliability); (2) clinical validity (sensitivity, specificity, and positive and negative predictive value) in relevant populations of patients; and (3) clinical utility (i.e., demonstration that the diagnostic information can be used to improve patient outcomes). The following is a summary of the key literature published to date.

Vertebral Fracture Assessment
Clinical Context and Test Purpose
The question addressed in this evidence review is whether there is sufficient evidence that screening for vertebral fracture assessment (VFA) using dual-energy x-ray absorptiometry (DXA) improves the net health outcome in patients at risk of having vertebral fractures compared with alternative approaches.

The following Patients, Interventions, Comparators, Outcomes, Timing, and Setting (PICOTS) were used to select literature to inform this review.
Patients
The relevant population of interest is individuals who are at risk of having vertebral fractures but are not known to have them.

Interventions
The relevant intervention of interest is VFA with densitometry by DXA.

Comparators
The primary comparator of interest is DXA alone for the assessment of bone mineral density (BMD). Spine radiography is also a comparator for diagnosing vertebral fractures. Radiography is used to confirm the occurrence of vertebral fractures but is not recommended as a routine component of osteoporosis assessment because of radiation exposure and inconvenience (i.e., the need for an additional procedure).

Outcomes
Outcomes of interest for diagnostic accuracy include test accuracy and test validity (e.g., sensitivity, specificity). The primary outcome of interest for clinical utility is morbid events, specifically the incidence of future clinical fractures.

Timing
VFA with densitometry by DXA would occur at the time of osteoporosis screening. The recommended age at which to start screening with DXA and the frequency of screening is addressed in national guidelines.

Setting
The tests are performed in a doctor's office or a radiology clinic.

Technical Reliability
VFA is performed using specialized software. Technical reliability measures (e.g., test-retest that apply to laboratory tests and medical devices), do not apply in this situation.

Clinical Validity
Systematic Reviews
Several recent studies have compared the diagnostic accuracy of VFA with standard radiography. A systematic review of studies was published by Lee et al (2016). They included studies with postmenopausal women and/or men 50 years and older that compared the diagnostic accuracy of VFA with DXA with spinal radiography. Seventeen studies met selection criteria; five were excluded because of inadequate description of methods or results. Of the remaining 12 studies, 4 examined postmenopausal women, 5 included osteoporotic patients (men and women), and 2 included both populations. Studies were heterogeneous, and thus reviewers did not pool study findings. Among the 8 studies that reported findings on a per-vertebral level, the sensitivity of VFA with DXA ranged from 70% to 93% and the specificity ranged from 95% to 100%. Nine studies reported findings on a per-patient level. Sensitivity ranged from 65% to 100% and specificity from 74% to 100%. Reviewers did not report separate analyses for the diagnostic accuracy of VFA with DXA in osteoporotic vs non-osteoporotic patients.

Nonrandomized Trials
One study included in the systematic review that was judged to have a low risk of bias was published in 2013 by Domiciano et al. Reviewers reported on 429 adults at least 65 years old who had VFA with densitometry and spine radiography on the same day. On VFA, vertebral fractures were identified in 77 (29.7%) of 259 women and in 48 (28.2%) of 170 men. Comparable numbers on spine radiographs were 74 (28.6%) of 259 women and 52 (30.6%) of 170 men. Compared with spine radiography, the sensitivity of VFA was 81.7% (95% confidence interval [CI], 73.9% to 88.1%) and the specificity was 92.7% (95% CI, 9.2% to 95.4%).
The diagnostic performance of VFA with DXA have tended to be lower in older studies. For example, in 2008 Ferrar et al evaluated the performance of vertebral assessment using a visual algorithm-based approach. Subjects in the low-risk group were women ages 55 to 79 years who were randomly selected from their general practitioners’ offices. Most had normal BMD or were osteopenic. Subjects in the high-risk group were recruited after a low-trauma fracture to the hip, forearm, or humerus. Most high-risk patients had osteopenia or osteoporosis. In per-patient analysis and including all poor or unreadable images, the sensitivity of VFA was 60% in the low-risk group and 81% in the high-risk group; specificity was 97% in both groups. Also, a 2005 study by Binkley et al compared VFA (GE Lunar densitometer) with radiography in 27 osteoporotic, 38 osteopenic, and 15 normal women. Blinded analysis correctly identified 17 of 18 radiographically evident grade 2 to 3 fractures (a false-negative rate, 6%). The study did not describe whether the grade 2 or 3 fractures were found in women with osteoporosis, osteopenia, or normal BMD. Also, only 11 (50%) of 22 grade 1 fractures were identified. Thirty vertebrae were classified as fractured when no fractures were present (38% false positive); 29 of these were grade 1 fractures by VFA with normal radiography. Also, VFA identified 40 grade 1 fractures, but only 11 (28%) were true-positive results. Also problematic is that results were compared only in vertebrae evaluable by VFA; 1 patient could not be evaluated due to poor image quality, and 66% of T4 to T6 vertebrae in other subjects could not be adequately visualized.

**Section Summary: Clinical Validity**

Several studies have compared VFA with radiography, and they were evaluated in a 2016 systematic review. The sensitivity of VFA compared with standard radiography reported in these studies varied. More recent studies have also reported higher diagnostic accuracy than older studies (i.e., sensitivities in the 80% to 99% range and specificities over 90%).

**Clinical Utility**

**Direct Evidence**

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Preferred evidence comes from randomized controlled trials. No RCTs comparing health outcomes in individuals screened with VFA plus bone densitometry using DXA with those screened with bone densitometry using DXA alone were identified.

**Chain of Evidence**

A chain of evidence for the clinical utility of VFA screening is based on evidence that VFA identifies appropriate candidates for treatment who would not otherwise be identified, and there is evidence that treatment in this population is beneficial. The chain involves evaluating:

1. evidence that VFA is accurate,
2. evidence that VFA identifies appropriate candidates for treatment who would not otherwise be identified, and
3. evidence that treatment in this population is actually beneficial.

The National Osteoporosis Foundation’s (NOF) 2014 guidelines recommends considering U.S. Food and Drug Administration (FDA)-approved medical treatment for the following groups of patients:

- "In those with hip or vertebral (clinical or asymptomatic) fractures"
- "In those with T-scores ≤ -2.5 at the femoral neck, total hip or lumbar spine by DXA"
- "In postmenopausal women and men age 50 and older with low bone mass (T-score between -1.0 and -2.5, osteopenia) at the femoral neck, total hip, or lumbar spine by DXA and a 10-year hip fracture probability ≥ 3% or a 10-year major osteoporosis-related fracture probability of ≥ 20% based on the USA-adapted WHO [World Health Organization] absolute fracture risk model (Fracture Risk Algorithm [FRAX])"

(The WHO algorithm is available online.)

Because patients with osteoporosis (T score, ≤ -2.5) diagnosed by DXA and patients with low bone mass and other risk factors for fracture would be treated regardless of vertebral fractures,
any incremental benefit using a VFA-inclusive strategy would accrue in the population without osteoporosis.

**VFA to Identify Candidates Who Would Not Otherwise Be Identified**

As stated above, the 2014 NOF guidelines recommended treating patients with osteoporosis, osteopenia, and other risk factors as well as those with hip or vertebral fractures (clinical or asymptomatic).

VFA has been used to identify candidates for treatment when patients with vertebral fractures do not fall into one of the other established categories. No studies were identified that specifically dealt with whether VFA could identify candidates for medication treatment who would not otherwise have been identified, but several studies are somewhat informative. Representative studies with larger sample sizes are described next.

A 2014 study by Kanterewiez et al in Spain collected data on a population-based cohort of 2968 postmenopausal women between the ages of 59 and 70 years. A total of 127 (4.3%) women had a vertebral fracture according to VFA. Among them, 48.0% had osteoporosis, and 42.5% had osteopenia. Moreover, 42.5% had previous fragility fractures, and 34.6% had a first-degree family history of fractures. Thus, VFA could identify women who would be eligible for fracture prevention therapy according to NOF guidelines (i.e., women who did not have osteoporosis, osteopenia plus a 10-year fracture risk, or other risk factors). The authors did not attempt to define this subgroup (e.g., they did not report data on women with normal BMD and other risk factors).

In 2013, Mrgan et al in Denmark published a retrospective study evaluating VFA with BMD in 3275 patients presenting for osteoporosis screening or evaluation of anti-osteoporotic medication; 85% were women. Vertebral fractures were found using VFA in 260 (7.9%) patients. Of them, 156 patients (4.8% of the total sample) had osteoporosis (i.e., BMD at least -2.5) and 104 (3.2% of the total sample) did not, according to BMD. The data suggested that up to 40% (104/250) patients with vertebral fractures identified would be eligible for treatment by NOF guidelines and might not have been identified were DXA alone used. Some patients, however, might have had osteopenia and other risk factors that would have led to their eligibility for treatment.

In 2011, Jager et al reported on 2424 consecutive patients (65% female) referred for BMD for a variety of reasons at a single center in the Netherlands. Participants underwent VFA with BMD during the same session. Vertebral fractures (reduction in the height of at least 20%) were detected in 541 (22%) patients. The prevalence of vertebral fractures was 14% (97/678) in patients with normal BMD and 21% (229/1100) in patients with osteopenia. Thus, 60.5% (326/541) of the patients with vertebral fracture did not have osteoporosis and would have been eligible for treatment based on NOF guidelines if they did not fall into another eligibility category (e.g., osteopenia with other risk factors). Most fractures had not been identified in the past. The vertebral fractures were previously unknown in 74% of patients with normal BMD and 71% of patients with osteopenia.

**Pharmacologic Treatment for Vertebral Fracture and Low Bone Mass**

Bisphosphonates decrease bone resorption and are the major class of drugs now used to treat osteoporosis.

**Randomized Controlled Trials**

Several subgroup analyses of large RCTs evaluating the efficacy of bisphosphonates in patients with low bone mass and/or baseline vertebral fractures have been published. The trials were not designed a priori to assess efficacy according to baseline vertebral fracture status or BMD categories. The Fracture Intervention Trial (FIT) study group was the first large multicenter study comparing the effects of treatment between osteoporotic women and women with low bone mass without existing vertebral fractures using the revised National Health and Nutrition Examination Survey cutoffs. This trial randomized 4432 women to alendronate or placebo and
analyzed the treatment group in 3 BMD categories (<-2.5 SD, -2.0 to -2.5 SD; -1.6 to -2.0 SD below the mean). Women with a BMD less than -2.5 SD had a statistically significant reduction in clinical and vertebral fractures over 4 years. The relative risk (RR) for all clinical fractures among patients with a BMD less than -2.5 SD was 0.6 (95% CI, 0.5 to 0.8). There was no significant reduction in all clinical fractures for women with higher BMD values (RR=1.1; 95% CI, 0.9 to 1.4), suggesting no benefit among patients with low bone mass or normal BMD.

Quandt et al (2005) reanalyzed FIT study data for the outcome of clinical vertebral fractures (symptomatic and diagnosed by a physician) and radiographically detected (assessed at surveillance intervals) vertebral fractures. A total of 3737 women at least 2 years postmenopausal with low bone mass (T score between -1.6 and -2.5) were included in the analysis. Among the women with low bone mass and existing radiographically detected vertebral fractures (n=940), the rate of subsequent clinical vertebral fractures was 6 (a rate of 43/10,000 person-years of risk) in the alendronate group and 16 (124/10,000 person-years of risk) in the placebo group. Alendronate treatment compared with placebo was accompanied by an RR of 0.3 (95% CI, 0.1 to 0.8) for clinical vertebral fractures and an RR of 0.5 (95% CI, 0.3 to 0.8) for radiographically detected fractures. Similar risk estimates were found for women having low bone mass without vertebral fractures, but absolute risks were lower (12 vs 81 fractures per 10,000 person-years for those without and with baseline fractures, respectively).

Kanis et al (2005) reanalyzed data on 1802 women at least 5 years postmenopausal from the Vertebral Efficacy with Risedronate Therapy (VERT) trials who were identified on the basis of a prior radiographically detected vertebral fracture regardless of BMD and had radiographs available at baseline and 3 years. Overall, there was a significantly lower rate of a new vertebral fracture in women with prior vertebral fracture randomized to treatment with risedronate (14.5%) than to placebo (22.3% p<0.001). In the group with a T score greater than -2.5, the rate of new femoral neck fractures was 50 (11%) of 519 in the risedronate group and 71 (15.5%) of 537 in the placebo group (p=0.049). In the osteoporotic group, for those with a T score of -2.5 or lower, the rate of new femoral neck fracture was 53 (18.7%) of 355 in the risedronate group and 92 (33.4%) of 318 in the placebo group (p<0.001). Findings were similar when the T score at the most severe skeletal site (femoral neck or lumbar spine) was used for stratification.

No RCTs were identified that evaluated the efficacy of bisphosphonate treatment in men with vertebral fractures and low bone density. Several trials have evaluated whether bisphosphonate treatment increases BMD in men at risk for bone loss (e.g., on androgen deprivation therapy). However, vertebral fractures were not assessed and, therefore, conclusions cannot be drawn about the potential benefit of VFA added to densitometry in at risk men.

Section Summary: Clinical Utility
Routine use of VFA with DXA will identify substantial numbers of patients with previously unrecognized vertebral fractures. Many of these vertebral fractures are found in patients without osteoporosis. Data are not available on how many of the vertebral fractures in nonosteoporotic patients were in patients who would not otherwise be eligible for treatment (i.e., those with osteopenia and other risk factors for fracture).

Evidence from the FIT and VERT studies has suggested that treatment of patients with low bone mass (but not osteoporosis) reduces further fractures. However, the FIT and VERT studies were post hoc subgroup analyses, which are considered to be exploratory. Also, vertebral fracture screening was done using radiography rather than VFA software. Advantages of the studies are that the 2 subgroup reanalyses had large sample sizes and used data from well-conducted randomized trials.

Currently, this chain of evidence is insufficient to determine whether treatment of patients with low bone density and vertebral fractures improves outcomes.
Summary of Evidence

For individuals who are at risk of having vertebral fractures but are not known to have them who receive VFA with densitometry by dual-energy x-ray absorptiometry, the evidence includes diagnostic accuracy studies and subgroup reanalyses of treatment studies. Relevant outcomes are test accuracy, test validity, and morbid events. There is a lack of direct evidence from screening trials that use densitometry with and without VFA improves health outcomes. Because direct evidence was not available, a chain of evidence was sought. Evidence was examined on the diagnostic accuracy of VFA in nonosteoporotic patients (i.e., those not already eligible for treatment), the ability of VFA to identify patients for treatment who would not otherwise be identified, and the effectiveness of treatment in this population. Diagnostic accuracy studies have reported variable findings; recent studies have suggested higher diagnostic accuracy of VFA overall compared with standard radiographs than older studies. Studies have found that VFA can identify patients without osteoporosis who may be appropriate candidates for treatment according to recommendations from the National Osteoporosis Foundation. However, there is limited evidence on the effectiveness of treatment in this population. No treatment data have been published in patients whose vertebral fracture had been identified using VFA software with densitometry. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Clinical Input from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests from Blue Cross Blue Shield Association, input was received from 5 physician specialty societies and 6 academic medical centers in 2014. One of the 5 specialty societies only submitted a practice statement and did not respond to questions. Input was mixed on whether vertebral fracture assessment using dual-energy x-ray absorptiometry is considered investigational. Input was also mixed on whether the diagnostic accuracy of vertebral fracture assessment using dual-energy x-ray absorptiometry is sufficiently high to justify its use as an alternative to plain radiographs. There was near-consensus agreement with National Osteoporosis Foundation recommendations regarding imaging to evaluate for vertebral fractures. Responders did not cite published literature to support the National Osteoporosis Foundation recommendations. Also, there was near-consensus that patients with vertebral fracture alone (i.e., no low bone mineral density and no other signs of osteoporosis) should be treated with medications to reduce fracture risk.

Practice Guidelines and Position Statements

National Osteoporosis Foundation

The National Osteoporosis Foundation’s 2014 guide to prevention and treatment of osteoporosis stated:

“A vertebral fracture is consistent with a diagnosis of osteoporosis, even in the absence of a bone density diagnosis, and is an indication for pharmacologic treatment with osteoporosis medication to reduce fracture risk. Most vertebral fractures are asymptomatic when they first occur and often are undiagnosed for many years. Proactive vertebral imaging is the only way to diagnose these fractures. The finding of a previously unrecognized vertebral fracture may change the diagnostic classification, alters future fracture risk and subsequent treatment decisions.”

The guide recommended that vertebral imaging tests be considered in the following patients:

- “All women age 70 and older and all men age 80 and older....
- Women age 65 to 69 and men age 75 to 79 when BMD [bone mineral density] T-score is -1.5 or below.
- Postmenopausal women age 50 to 64 and men age 50 to 69 ... with specific risk factors:
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- Low-trauma fracture...
- Historical height loss of 1.5 in. or more (4 cm)
- Prospective height loss of 0.8 in. or more (2 cm)
- Recent or ongoing long-term glucocorticoid treatment.”

**International Society for Clinical Densitometry**

In 2013, the International Society for Clinical Densitometry updated its recommendations for selecting patients for vertebral fracture assessment (VFA).15 The new recommendations were simpler compared with the 2007 recommendations and were intended to be easier to use in clinical practice. Lateral spine imaging with either standard radiography or densitometric VFA is indicated for patients with a T score of less than -1.0 when at least 1 of the following factors are present:

- “Women age ≥70 yr or men ≥80 yr
- Historical height loss >4 cm (>1.5 inches)
- Self-reported but undocumented prior vertebral fracture
- Glucocorticoid therapy equivalent to ≥5 mg of prednisone per day for ≥3 mo.”

**American Association of Clinical Endocrinologists and American College of Endocrinology**

The 2016 joint guidelines from the American Association of Clinical Endocrinologists and American College of Endocrinology on the diagnosis and treatment of postmenopausal menopause included the following recommendation on VFA.16 Their joint recommendations are similar to those of the International Society for Clinical Densitometry in 2013.

**Endocrine Society**

In 2012 Endocrine Society recommended pharmacologic therapy for men at high risk for fracture.17 Risk includes but is not limited to the following criteria:

- “Men who have had a hip or vertebral fracture without major trauma.
- Men who have not experienced a spine or hip fracture but whose BMD of the spine, femoral neck, and/or total hip is 2.5 SD or more below the mean of normal young white males.
- In the United States, men who have a T-score between -1.0 and -2.5 in the spine, femoral neck, or total hip plus a 10-yr risk of experiencing any fracture ≥20% or 10-yr risk of hip fracture ≥3% using FRAX [Fracture Risk Algorithm]; further studies will be needed to determine appropriate intervention levels using other fracture risk assessment algorithms....
- Men who are receiving long-term glucocorticoid therapy in pharmacologic doses (e.g. prednisone or equivalent >7.5 mg/d), according to the 2010 guidelines of the American Society of Rheumatology.”

**American College of Physicians**

The American College of Physicians’ (ACP) 2017 guidelines on the treatment of low bone density or osteoporosis include the following recommendations (see Table 1).18

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>GOE</th>
<th>QOE</th>
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<td>“ACP recommends that clinicians offer pharmacologic treatment with bisphosphonates to reduce the risk for vertebral fracture in men who have clinically recognized osteoporosis.”</td>
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<td>Low</td>
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<tr>
<td>“ACP recommends that clinicians should make the decision whether to treat osteopenic women 65 years of age or older who are at a high risk for fracture based on a discussion of patient preferences, fracture risk profile, and benefits, harms, and costs of medications.”</td>
<td>Weak</td>
<td>Low</td>
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</table>

GOE: grade of evidence; QOE: quality of evidence.

**North American Menopause Society**

The North American Menopause Society’s 2010 position statement on management of osteoporosis did not include a recommendation for or against VFA as part of the screening...
process.\textsuperscript{19} The statement indicated that vertebral fracture must be confirmed by lateral spine radiographs or VFA visualization of fracture at the time of BMD testing.

**U.S. Preventive Services Task Force Recommendations**

The U.S. Preventive Services Task Force published updated recommendations on osteoporosis screening in 2010.\textsuperscript{20} The recommendations included: “Current diagnostic and treatment criteria rely on dual-energy x-ray absorptiometry of the hip and lumbar spine.” VFA was not specifically mentioned. As of August 2017, the Task Force’s website stated that an updated recommendation statement on screening for osteoporosis fractures is in development.

**Medicare National Coverage**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

**Ongoing and Unpublished Clinical Trials**

A search of ClinicalTrials.gov in August 2017 did not identify any ongoing or unpublished trials that would likely influence this review.

**References**


**Documentation for Clinical Review**

- No records required

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

**IE**

The following services may be considered investigational.

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<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
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<td>CPT®</td>
<td>77085</td>
<td>Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (e.g., hips, pelvis, spine), including vertebral fracture assessment</td>
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<td>77086</td>
<td>Vertebral fracture assessment via dual-energy X-ray absorptiometry (DXA)</td>
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<td>ICD-10 Procedure</td>
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<td>Plain Radiography of Cervical Spine, Densitometry</td>
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<td></td>
<td>BR09ZZ1</td>
<td>Plain Radiography of Lumbar Spine, Densitometry</td>
</tr>
</tbody>
</table>
### Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

### Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.